UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,889	09/06/2006	Khalid Sayood	24742-0017US1	5917

26191   7590   04/29/2010
FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER
NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
04/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

	Application No.	Applicant(s)
Office Action Summary	10/561,889	SAYOOD ET AL.
	Examiner	Art Unit
	RUSSELL S. NEGIN	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>11 January 2010</u>.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-23</u> is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) <u>1-23</u> is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on <u>21 December 2005</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All   b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date <u>12/21/2005</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____ .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 11 January 2010 is acknowledged. The traversal is based on the ground(s) that the recited subject matter asserted to be not free over the art of Felsenstein [J. Mol. Evol., 1981, volume 17, pages 368-376] is free over this particular piece of prior art. This argument is found to be persuasive and Groups I and II are rejoined.

Consequently, claims 1-23 are both pending and examined in the instant Office action.

Information Disclosure Statement

The Information disclosure statement filed on 21 December 2005 has been considered.

Oath/Declaration

The declaration filed on 6 September 2005 is defective because all of the copies of the declaration do not list each inventor. In this instance, the copy of the oath signed by Khalid Sayood does not include the name of the third inventor, Steven H. Hinrichs. See MPEP 201.03 II B and MPEP 605.04(a) for rules governing the signatures and listing of inventors on oaths and declarations submitted for an invention.

Priority

It is noted that while the declaration filed on 6 September 2006 claims

benefit to provisional application 60/479,668 filed on 19 June 2003, this benefit

claim is not proper for the reasons discussed below.

Specifically, if applicant desires to claim the benefit of a prior-filed

application under 35 U.S.C. 119(e), a specific reference to the prior-filed

application in compliance with 37 CFR 1.78(a) must be included in the first

sentence(s) of the specification following the title or in an application data sheet.

For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must

include the relationship (i.e., continuation, divisional, or continuation-in-part) of

the applications.

If the instant application is a utility or plant application filed under 35

U.S.C. 111(a) on or after November 29, 2000, the specific reference must be

submitted during the pendency of the application and within the later of four

months from the actual filing date of the application or sixteen months from the

filing date of the prior application. If the application is a utility or plant application

which entered the national stage from an international application filed on or after

November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference

must be submitted during the pendency of the application and within the later of

four months from the date on which the national stage commenced under 35

U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application.

See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a

failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where

applicable, within this time period is considered a waiver of any benefit of such

prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim

filed after the required time period may be accepted if it is accompanied by a

grantable petition to accept an unintentionally delayed benefit claim under 35

U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1)

the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or

(a)(5) to the prior application (unless previously submitted), (2) a surcharge under

37 CFR 1.17(t), and (3) a statement that the entire delay between the date the

claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed

was unintentional. The Director may require additional information where there is

a question whether the delay was unintentional. The petition should be

addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450,

Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the

time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the

specification or an application data sheet (ADS) as required by 37 CFR 1.78(a)

(e.g., if the reference was submitted in an oath or declaration or the application

transmittal letter), and the information concerning the benefit claim was

recognized by the Office as shown by its inclusion on the first filing receipt, the

petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not

required. Applicant is still required to submit the reference in compliance with 37

CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification

or an ADS. See MPEP § 201.11.

Consequently, the benefit date of claims 1-23 is **NOT** 19 June 2003, but instead it is **21 June 2004**.

Even if this claim of benefit to the provisional is corrected, there are other reasons for denying benefit of a subset of claims to provisional application 60/479,668 filed on 19 June 2003 for the reasons discussed below.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/479,668, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Specifically, claims 3-9 and 13-17 require placement of sets of two or three nucleotides appearing in a specific order in a sequence into a sequential sequence of two or three nucleotides. While provisional application 60/479,668 teaches appending one sequence to the next sequence (see last paragraph on

page 1 and first paragraph on page 2 of 60/479,668), provisional application

60/479,668 nowhere requires sequential placement of sets of two or three

consecutive nucleotides.

Additionally, claims 2, 12, and 20-21 require comparing two nucleotide

sequences obtained form the same source wherein one of the two sequences is

placed in a database. While the first paragraph on page 1 of 60/479,668 requires

placement of unknown sequences in DNA databases. Application 60/479,668

nowhere requires the unknown sequences to be obtained from the same source

as the known nucleotide sequence.

Consequently, IF THE **BENEFIT CLAIM** IS **CORRECTED**, claims 2-9, 12-

17, and 20-21 would still have the benefit date of 21 June 2004 while claims 1,

10-11, 18-19, and 22-23 would have a benefit date of 19 June 2003.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or
composition of matter, or any new and useful improvement thereof, may obtain a patent
therefor, subject to the conditions and requirements of this title.

Claims 1-23 are rejected under 35 U.S.C. 101 because the claimed

invention is directed to non-statutory subject matter.

Claims 1-9, 11-17, and 22 are drawn to a method of determining sets of

nucleotides in nucleotide sequences and their associated distances.

This rejection is in line with the recent decision in *In re Bilski*, 545 F.3d

943, 88 USPQ2d 1385 (Federal Circuit, 2008). In the instant case, the claims

are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. In order for a claim to provide a practical application, the claim **must meet** the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept **may have a practical application,** a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus <u>or</u> (2) transforms a particular article to a different state or thing.

In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of information manipulation. For example independent claim 1 recites steps of "receiving a first and second nucleotide" and "comparing the first set of nucleotides to a first nucleic acid sequence." Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

Further, the method claims (claims 1-9, 11-17, and 22) are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not tied to any **particular apparatus** or **machine**" and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

It is noted that instant claims 10, 18, and 23 are drawn to computer readable media for executing the claims reciting the methods described above. While lines 6-14 of page 3 of the specification disclose that the algorithm can be performed on a "universal computer," the specification is silent on what recited computer readable media. Consequently, in the absence of such a disclosure, computer readable media are interpreted to encompass carrier waves, which, per se, are not statutory.

Claims 19-21 are drawn to a system for determining sets of nucleotides in nucleotide sequences and their associated distances. Specifically, claims 19-21 recite "a receiving component," "a comparing component," "a storing component," and "a second receiving module." In the absence of a structural disclosure in the specification, these components and modules are interpreted to encompass embodiments of a computer program. Computer programs, per se, are not statutory.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

INDEFINITENESS

Claims 7-9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the first nucleic acid sequence" in claim 9. There is insufficient antecedent basis for this limitation in the claim. However, both line 5 of claim 1 and line 2 of claim 8 recite "a first nucleic acid sequence." As a result, it is unclear as to the antecedent basis of "the first nucleic acid sequence" in claim 9 (if it is in claim 1 or claim 8).

Claims 7-9 and 17 are indefinite because each of the claims recites sums and/or differences of units stored for nucleic acid sequences. In each instance, it is unclear as to what constitutes a sum of a unit of nucleic acid sequences. In one interpretation, a sum of units of nucleic acid sequences represents appending the second nucleic acid sequence to the first nucleic acid sequence, and a difference represents the opposite (I.e. removal of a subsequence from a sequence). Pages 6-7 of the specification denote such an appending of multiple nucleic acid sequences, but as a product and not a sum (i.e. sequence R is the appending of sequence Q to sequence S and is equivalent to SQ and NOT S + Q). In another interpretation, summing (and differencing) of units representing nucleic acids is indicated by sums (and differences) of SCORES representing each sequence and subsequence. The equations on pages 8-9 of the specification list equations showing distance measures as a result of summing

and differencing scores of sequences and subsequences of nucleic acids

sequences.

As explained above, since claims 7-9 and 17 do not indicate a form of

score to be used, for the purpose of examination, summing and differencing

sequences is interpreted to be appending and removing subsequences from

sequences, respectively (i.e. the first interpretation discussed above).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-16, and 18-21 are rejected under 35 U.S.C. 102(b) as

being anticipated by Varre et al. [Bioinformatics, volume 15, 1999, pages 194-

202].

Discussion of Independent claims 1, 11, and 19:

Independent claim 1 is drawn to a method of determining whether a set of

nucleotides is within a first nucleic acid sequence. The method comprises

receiving a first and a second nucleotide of a second nucleic acid sequence

wherein the second nucleotide is after the first nucleotide. The method also

comprises combining the first and second nucleotide into a sequential set. The

method also comprises comparing the first set of nucleotides to a first nucleic

acid sequence to determine whether the first set of sequential nucleotides is within the first nucleic acid sequence.

Independent claim 11 is drawn to creating a database of nucleotide units for a first nucleic acid sequence. The method comprises receiving a first nucleotide of a first nucleic acid sequence, determining whether the first nucleotide has been stored in a database as a unit for the first nucleic acid sequence, and if not, storing the first nucleotide as a storing the first nucleotide as a unit for the first nucleic acid sequence.

Independent claim 19 is drawn to similar subject matter as independent claim 1, except as a system and not a method.

The article of Varre et al. studies transformation distances as in a family of dissimilarity measures in oligonucleotide sequences [title].

Specifically, Figure 1 on page 197 of Varre et al. lists a database comprising two sequences of RNA: a target sequence and a source sequence. Figure 1 of Varre et al. labels by letters, brackets, and dashes alongside each sequence sequential subsequences or a plurality of adjacent and subsequent nucleotides within the second sequence that occur within the first sequence. All of the nucleotides, whether in the first sequence, in the second sequence, labeled with bracketed alphabetic letters, or not labeled are stored in the sequence database of Figure 1 of Varre et al.

With regard to claim 2, since every nucleotide of each sequence of Figure 1 of Varre et al. is stored in the database of Figure 1 of Varre et al., this database

encompasses sets of nucleotides that are not within the first nucleic acid

sequence.

With regard to claims 3-5, all of the subsequences labeled with brackets

have more that two sequential nucleotides in a row that are common between the

two nucleotide sequences.

With regard to claim 6, as explained above, since every nucleotide of each

sequence of Figure 1 of Varre et al. is stored in the database of Figure 1 of Varre

et al., this database encompasses sets of nucleotides that are not within the first

nucleic acid sequence (which comprises more than two nucleotide bases in a

row).

With regard to claims 10 and 18, the computer implementation using

computer readable media is disclosed in Figure 3 and the "Implementation"

section on page 199 of Varre et al.

With regard to claims 12-16 and 20-21, as explained above, the bracketed

subsequences in Figure 1 of Varre et al. each have a plurality of bases (all

brackets comprise more than two bases) in a sequential row that are common to

both sequences. Figure 1 of Varre et al. itself is a database containing every

base in both sequences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for

all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described
as set forth in section 102 of this title, if the differences between the subject matter sought to
be patented and the prior art are such that the subject matter as a whole would have been
obvious at the time the invention was made to a person having ordinary skill in the art to which
said subject matter pertains. Patentability shall not be negatived by the manner in which the
invention was made.

This application currently names joint inventors. In considering

patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35

U.S.C. 103(a).

Claims 7-9, 17, and 22-23 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Varre et al. as applied to claims 1-6, 10-16, and 18-21 above,

in further view of Queen et al. [Nucleic Acids Research, Volume 12, 1984, pages

581-599].

Claims 7 and 17 are further limiting comprising determining the sum of the

units stored for the second nucleic acid sequence.

Claim 8 is further limiting comprising determining the difference between

total number of units stored for a first nucleic acid sequence and the total number

of units stored for the second nucleic acid sequence. Claim 9 is further limiting

comprising utilizing the difference to determine the distance between the first

nucleic acid sequence and the second nucleic sequence.

Claim 22 is drawn to a method of determining the distance between two

nucleic acid sequences. The method comprises determining the number of

words in a first nucleic acid sequence. The method also comprises combining

the first sequence with a second nucleic acid sequence to make a combined

nucleic acid sequence. The method also comprises determining the number of

words in the combined nucleic acid sequence. The method also comprises

determining the difference between the number of words in the combined nucleic

acid sequence and the first nucleic acid sequence to determine the distance

between the first nucleic acid sequence and the second nucleic acid sequence.

Claim 23 is drawn to computer readable media for carrying out the method

of claim 22.

The article of Varre et al. teaches a method, system, and computer

program for creating and analyzing sequences of nucleic acids, as discussed

above. Furthermore, the entire list of sequences in Figure 1 of Varre et al.

comprised the sum of each of the sequences. The bracketed subsequences of

the sequences in Figure 1 of Varre et al. are interpreted to be "words" present in

both sequences. Since the letters are "numbered" from a to k, there are a total of

eleven words common to both sequences. The degree of common words

between each of the sequences suggests the degree of difference or distance

between to the two sequences in Figure 1 of Varre et al.

However, the article of Varre et al. does not show summing, combining, and differencing of sequences by inserting and deleting subsequences into sequences as required in view of the interpretation of the indefiniteness rejection described above.

The article of Queen et al. studies a comprehensive sequence analysis program for the IBM personal computer [title]. Specifically, Queen et al. uses an IBM personal computer to analyze biological sequences that include nucleic acid sequences [abstract]. In accomplishing this goal, the first paragraph on page 588 of Queen et al. describes deleting and inserting regions into sequences.

It would have been obvious to someone of ordinary skill in the art at the time of the invention to modify the sequence database analysis of Varre et al. by use of the insertion and deletion of sequences into larger sequences as in Queen et al. wherein the motivation would have been that the modification of sequences by inserting and deleting sequences provides a user-accessible and *in silico* means for editing sequence data to incorporate useful subsequences and to dispose of unnecessary subsequence data [see first full paragraph on page 588 of Queen et al.].

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform

with the notices published in the Official Gazette, 1096 OG 30 (November 15,

1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-

8300.

Any inquiry concerning this communication or earlier communications from

the examiner should be directed to Russell Negin, whose telephone number is

(571) 272-1083. The examiner can normally be reached on Monday-Friday from

8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be

reached at (571) 272-0720.

Information regarding the status of the application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information on the PAIR system, contact the

Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/
Examiner, AU 1631
21 April 2010